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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,655	03/01/2006	Stefan Golz	004974.01084	4692

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EXAMINER	
LI, RUIXIANG	
ART UNIT	PAPER NUMBER
1646	
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12/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,655	GOLZ ET AL.	
	Examiner	Art Unit	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, and 4-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicant's amendment filed on 11/06/2008 has been entered. Claims 1 and 2 are amended. Claim 3 is canceled. Claims 1, 2, and 4-11 are pending and under consideration.

Withdrawn Objections and/or Rejections

The rejection of claims 1-11 under 35 U.S.C. 112, first paragraph, is withdrawn in view of amended independent claims 1 and 2.

The rejection of claims 1-11 under 35 U.S.C. 112, second paragraph is withdrawn in view of amended independent claims 1 and 2.

The rejection of claims 1-11 under 35 U.S.C. 102 (b) as being anticipated by Aiyar et al. (U. S. Patent No. 6,159,700, Dec. 12, 2000) is withdrawn in view of amended independent claims 1 and 2.

Title

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections under 35 USC § 112, 1st paragraph

(i). The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(ii). Claims 1, 2, and 4-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. Ex Parte Forman, 230 USPQ 546 (Bd Pat. App. & Int. 1986); In re Wands, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claim 1 is drawn to a method of screening for therapeutic agents useful in the treatment of cancer in a mammal, comprising i) contacting a test compound with a GPR14 polypeptide, wherein the GPR 14 polypeptide is at least 90% homologous to the amino acid sequence of SEQ ID NO: 2; ii) detecting binding of the test compound to the

GPR14 polypeptide; and iii) determining if the test compound has an effect on a symptom of the cancer in an in vivo assay; whereas claim 2 is drawn to a method comprising i) contacting a test compound with a GPR14 polypeptide, wherein the GPR 14 polypeptide is at least 90% homologous to the amino acid sequence of SEQ ID NO: 2; ii) determining an activity of a GPR14 polypeptide in the presence and absence of the test compound"; and iii) determining if the test compound has an effect on a symptom of the cancer in an in vivo assay. Claims 4-11 depend from claim 1. The claims do not recite any functional activities for the GPR14 polypeptide variants. The claims are broad because they do not recite any functional limitations for the GPR14 polypeptide variants and encompassing a method of identifying a test compound that is useful for treating a long list of cancers.

The specification discloses that human GPR14 is highly expressed in the following cancer tissues: thyroid tumor, stomach tumor, colon tumor, lung tumor, breast tumor, and ovary tumor (page 33, line 30). The specification also states that the expression in the above mentioned tissue demonstrates that the human GPR14 or mRNA can be utilized to diagnose of cancer. The specification further states that additionally, the activities of the human GPR14 can be modulated to treat cancer (page 67, lines 1-3).

However, the specification does not disclose any particular activities that can be modulated to treat cancer, such as lung cancer. The specification fails to disclose a causal link between human GPR14 activity and a particular cancer, such as lung cancer

and fails to provide evidence showing that a compound that binds to GPR14 or modulates the activity can be used in the treatment of cancer, such as lung cancer. There is no guidance and/or working examples with respect to the activities of the GPR14 receptor that can be used to identifying a compound useful in the treatment of cancer. One skilled in the art would first have to determine whether there is a causal link between human GPR14 activity and a particular cancer or an activity of the GPR14 polypeptide that can be modulated to treat cancer.

Moreover, while disclosing a human GPR14 of SEQ ID NO: 2, the specification does not provide sufficient guidance and/or working examples with respect to how to make and use the genus of GPR14 polypeptides in the context of the claimed method. The specification fails to disclose a variant of the human GPR14 of SEQ ID NO: 2 that has a particular activity and is useful for identifying a compound useful in the treatment of cancer. Furthermore, the specification does not provide any guidance and/or working example with respect to how to determine an effect of a test compound on a symptom of cancer the in vivo assay.

The prior art teaches a human GPR 14 and a rat GPR14 (see, e.g., US Patent No. 6,159,700, Dec. 12, 2000). However, the prior art does not provide compensatory structural or correlative teachings to enable one skilled in the art to make and use the encompassed GPR14 polypeptide variants. More importantly, the prior art is silent regarding the role of the GPR14 polypeptide of SEQ ID NO: 2 in cancer. It is

unpredictable whether a test compound that binds to the GPR14 polypeptide or modulates activities recited in the claims is useful in the treatment of cancer. It would require large quantity of experimentation to determine whether there is a causative link between the GPR14 polypeptide of SEQ ID NO: 2 and cancer, such as lung cancer and whether an agonist or antagonist of the GPR14 polypeptide of SEQ ID NO: 2 is useful in the treatment of cancer.

Accordingly, in view of the various factors, it would take undue experimentation for one skilled in the art to make and use the instantly claimed methods.

(iii). Claims 1, 2, and 4-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Possession may be shown, for example, by describing an actual reduction to practice of the claimed invention. A specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose.

It is not the case here. Claim 1 is drawn to a method of screening for therapeutic agents useful in the treatment of cancer in a mammal, comprising i) contacting a test compound with a GPR14 polypeptide, ii) detecting binding of the test compound to the GPR14 polypeptide; and iii) determining if the test compound has an effect on a symptom of the cancer in an in vivo assay; whereas claim 2 is drawn to a method comprising i) contacting a test compound with a GPR14 polypeptide, ii) determining an activity of a GPR14 polypeptide in the presence and absence of the test compound"; and iii) determining if the test compound has an effect on a symptom of the cancer in an in vivo assay. Claims 4-11 depend from claim 1. Since there is no nexus between ii) and iii), the claims, as written, encompass two different unrelated methods in each of the claims: detecting binding of the test compound to the GPR14 polypeptide and determining if the test compound has an effect on a symptom of the cancer in an in vivo assay; or determining an activity of a GPR14 polypeptide in the presence and absence of the test compound and determining if the test compound has an effect on a symptom of the cancer in an in vivo assay.

The instant specification fails to describe an actual reduction to practice of the claimed invention. There is no disclosure of an in vivo assay in which an effect of a test compound on a symptom of the cancer can be tested. There is no showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claims and determined that the invention would work for its intended purpose. Accordingly, one skilled in the art would not recognize from the disclosure that the

Applicants were in possession of the claimed methods at the time the application was filed.

(iv). Claims 1, 2, and 4-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Amended claims 1 and 2 recite "determining if the test compound has an effect on a symptom of the cancer in an in vivo assay", which introduces new matter. In the response filed on 11/06/2008 (page 5), Applicants state that in vitro assay testing is disclosed on page 39, lines 23-26 and page 40, lines 9-13. However, careful examination of the specification indicates that there is no support for such an amendment in the specification: "determining if the test compound has an effect on a symptom of the cancer in an in vivo assay". In contrast, the specification (page 39, lines 23-26) merely discloses, "...determining which of these compounds have an effect on symptoms or diseases regarding the hematological and cardiovascular diseases, disorders of the peripheral and central nervous system, COPD, asthma, genitor-urological disorders and inflammation diseases in an in vivo assay." Any particular cancer is not listed here. Likewise, the specification disclosure at page 40 (lines 9-13) does not provide support for the amendment neither.

Claim Rejections Under 35 U.S.C. §112, 2nd Paragraph

(i). The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(ii). Claims 1, 2, and 4-11 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how to determine if the test compound has an effect on a symptom of the cancer in an in vivo assay, thereby identifying a therapeutic agent useful in the treatment of cancer. Claims 4-11 are rejected as dependent claims from claim 1.

(iii). Claims 2 and 4-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite because it recites, in part ii), a limitation, "wherein the activity is reflected by an observable change in the level in adenylayte cyclase activity...". It is unclear what the metes and bounds of the limitation are since the specification does not define the limitation unambiguously. Claims 4-11 are rejected as dependent claims from claim 2.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/
Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.
December 23, 2008